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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
PEFFLEY, MICHAEL F

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 12/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/006,088	Applicant(s) SLIWA ET AL.	
	Examiner Michael Peffley	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 December 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *61-79* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *61-79* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Priority

It is noted that in addition to the applications recited in the Cross Reference to Related Applications section of the specification there are numerous other co-pending applications which disclose and claim very similar and/or identical subject matter. In accordance with MPEP 704.11(a) subsection G, applicant is respectfully requested to disclose all of the co-pending applications, particularly those which contain claims drawn to similar/identical subject matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 64 and 72-79 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 64 is unclear with the scope of the claim, particularly since claim 63 (from which claim 64 depends) sets forth "an ablating element", and claim 64 recites "a plurality of ablating elements". In is not clear if the plurality of ablating elements are in addition to the single ablating element, of if the single ablating element is one of the plurality of ablating elements recited in claim 64.

Claim 72 is unclear with the statutory class of the invention. The preamble recites "A system for ablating tissue with ultrasound comprising the steps of" which implies two different statutory classes of invention are being claimed (i.e. method and apparatus). The claims must be directed to a single statutory class of invention.

Similarly, the dependent claims are unclear, particularly since some are directed to specific method steps and other are directed to apparatus limitations.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 61, 63-66 and 72-75 are rejected under 35 U.S.C. 102(b) as being anticipated by Marcus et al ('484).

Marcus et al disclose an apparatus which includes a body (52) which supports a phased array of ultrasonic transducers. The transducers focus ultrasonic energy to tissue for the ablation of tissue. It is noted that movement of the device will serve to move the focus of the array of transducers. A control system is used to turn the ablation energy on or off depending on sensed tissue conditions. This is tantamount to controlling/changing at least one of power, period of time and location of focus.

Claims 61-66, 72-75 and 78 are rejected under 35 U.S.C. 102(b) as being anticipated by Cain et al ('657).

Cain et al disclose an array of focused ultrasonic transducers used to ablate cardiac tissue (abstract). A controller is used to refocus the beam and control the output of the individual transducers (Summary of the Invention). The Figures show the divergent nature of the energy. It is noted that claim 65 does not state in which direction

the focal energy diverges (i.e. diverges away from the probe, or towards the probe). It only recites that when viewed perpendicular to the focal axis, the energy beam is divergent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 66-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cain et al ('657).

The Cain et al device has been addressed previously. Cain et al fail to disclose the specific focal lengths used or the particular frequencies used. The examiner maintains that one of ordinary skill in the art would obviously recognize the acceptable range of focal lengths and frequencies which could advantageously be used in a given procedure.

To have provided the Cain et al system with any reasonable focal length or frequency distribution for the focused array would have been an obvious consideration for one of ordinary skill in the art and dependent on the particular procedure, tissue and/or desired results.

Claims 67-71, 76 and 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marcus et al ('484) in view of the teaching of Negus et al ('848).

Marcus et al fail to disclose a means to monitor tissue thickness and means to assess the degree of contact with tissue of the ablation device. Marcus et al also fail to disclose the specific operating parameters of the system (i.e. focal length, frequency).

With regard to claims 67-71, Marcus et al disclose several studies which set forth various methodologies and parameters used to treat cardiac tissue. These methodologies include multiple delivery of energies at various frequencies, time durations and energy levels (see columns 8+). To have provided any specific focal length or treatment regimen (i.e. changing frequencies) with the Marcus et al device is deemed an obvious consideration for one of ordinary skill in the art, particularly since Marcus et al teach that various operating levels are contemplated.

Negus et al disclose an analogous ablation device for the treatment of cardiac tissue. The device includes numerous energy delivery modalities, including ultrasonic energy, and specifically teach means on the catheter for sensing tissue contact and tissue thickness (note columns 5 and 6). It is also noted that Marcus et al disclose tissue impedance monitoring electrodes, of which such a signal serves as an indication of tissue contact.

To have provided the Marcus et al system with a means to determine tissue contact and tissue thickness to control the delivery of ablation energy to tissue would have been an obvious modification for one of ordinary skill in the art, particularly since Negus et al teach the use of such parameters to control an ablation operation with an ultrasonic energy delivery device.

Double Pat nting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 61-79 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 96-114 of copending Application No. 09/614,991. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 61-79 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 67-71 of copending Application No. 09/698,639. Although the conflicting claims are not identical,

they are not patentably distinct from each other because the particular focal lengths and arrangements of the transducers is deemed an obvious consideration for one of ordinary skill in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 61-79 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 67 of copending Application No. 09/699,150. Although the conflicting claims are not identical, they are not patentably distinct from each other because the particular focal length and number of transducers is deemed to be an obvious consideration for one of ordinary skill in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 61-79 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 74-81 of copending Application No. 10/008,997. Although the conflicting claims are not identical, they are not patentably distinct from each other because the use of a focused ultrasound transducer is deemed an obvious consideration for one of ordinary skill in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 61-79 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 65-70 of copending Application No. 10/006,064. Although the conflicting claims are not identical, they are not patentably distinct from each other because the particular spacing of the transducers is deemed to be an obvious consideration for one of ordinary skill in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hissong ('531) and Sanghvi et al ('692) disclose other ablation elements which teach focused ultrasonic transducers for treating tissue.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (703) 308-4305. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0994. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Michael Peffley
Primary Examiner
Art Unit 3739

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December 10, 2002